House of Representatives

File No. 793

General Assembly

January Session, 2017

(Reprint of File No. 189)

Substitute House Bill No. 7118
As Amended by House Amendment
Schedule "B"

Approved by the Legislative Commissioner
May 25, 2017

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2017*):

(a) For the purposes of section 20-579 and this section:

(1) "Biological product" has the same meaning as provided in 42 USC 262;

[(1)**]** (2) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

[(2)**]** (3) "Generic name" means the established name designated in the official United States Pharmacopoeia-National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of said publications;

(4) "Interchangeable biological product" means a biological product

that: (A) The federal Food and Drug Administration has licensed and determined to meet the standards for interchangeability pursuant to 42 USC 262(k)(4), or (B) is therapeutically equivalent to another biological product, as set forth in the latest edition of or supplement to the federal Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations";

[(3)**]** (5) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen;

[(4)**]** (6) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

[(5)**]** (7) "Epilepsy" means a neurological condition characterized by recurrent seizures; and

[(6)**]** (8) "Seizures" means a disturbance in the electrical activity of the brain. **[**; and**]**

[(7) "Antiepileptic drug" means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.**]**

(b) Except as limited by subsections **[**(c), (e) and (i)**]** (f), (h) and (l) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for

consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) Except as limited by subsections (f), (h) and (l) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a biological product for a prescribed biological product if: (1) It is an interchangeable biological product, and (2) the practitioner has not specified, in the manner described in subsection (f) of this section, that there shall be no substitution for the prescribed biological product.

(d) (1) Upon the dispensing of an interchangeable biological product to a patient, the pharmacist or a duly authorized agent of the pharmacist shall inform the patient or a representative of the patient of a substitution of an interchangeable biological product for a prescribed biological product. Not later than forty-eight hours after the pharmacist has informed the patient or representative of the patient of the substitution, the pharmacist shall make an entry documenting the substitution in a manner authorized pursuant to subsection (m) of this section, and (2) prior to delivering an interchangeable biological product to a patient through mail, shipment or parcel delivery service, the pharmacist shall notify the patient or a representative of the patient by telephone to inform the patient or representative when the interchangeable biological product will be delivered. The patient or representative of the patient may make a request of the pharmacy that the patient or representative be present to sign for delivery of the interchangeable biological product. Not later than forty-eight hours after contacting the patient, the pharmacist shall make an entry documenting compliance with this subdivision in the patient's medical or pharmacy record, in a manner authorized pursuant to subsection (m) of this section.

(e) Upon the dispensing of an interchangeable biological product, but not later than forty-eight hours following the dispensing of such product, the pharmacist shall inform the prescribing practitioner by facsimile, telephone or electronic transmission of the substitution of such interchangeable biological product for a prescribed biological product.

[(c)**]** (f) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product or prescribed biological product specified on any prescription form, provided (1) for written prescriptions, the practitioner shall specify on the prescription form that the drug product or prescribed biological product is "brand medically necessary" or "no substitution", (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

[(d)**]** (g) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

[(e)**]** (h) A pharmacist may substitute a drug product under subsection (b) or interchangeable biological product under subsection (c) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

[(f)**]** (i) Except as provided in subsection **[**(g)**]** (j) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section or an interchangeable biological product as authorized by subsection (c) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product or interchangeable biological product. If the dispensed drug product or interchangeable biological product does not have a brand name, the prescription label shall indicate the generic name of the drug product or the nonproprietary name of the interchangeable biological product dispensed along with the name of the manufacturer of the drug **[**manufacturer or distributor**]** product or interchangeable biological product.

[(g)**]** (j) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug or biological product in the container unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

[(h)**]** (k) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection **[**(d)**]** (g) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

[(i)**]** (l) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not fill the prescription by using a different drug manufacturer or distributor of the prescribed drug or biological

product, unless the pharmacist (1) provides prior notice of the use of a different drug or biological product manufacturer or distributor to the patient and the prescribing practitioner, and (2) obtains the written consent of the patient's prescribing practitioner. For purposes of obtaining the consent of the patient's prescribing practitioner required by this subsection, a pharmacist shall notify the prescribing practitioner via electronic mail or facsimile transmission. If the prescribing practitioner does not provide the necessary consent, the pharmacist shall fill the prescription without such substitution or use of a different drug or biological product manufacturer or distributor or return the prescription to the patient or to the patient's representative for filling at another pharmacy. If a pharmacist is unable to contact the patient's prescribing practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of section 20-616. For purposes of this subsection, "pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy" does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

(m) Not later than forty-eight hours following the dispensing of an interchangeable biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer of the product. The entry shall be made in a manner that provides notice to the prescriber and may be made through one of the following means: (1) An interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacy benefit management system, or (4) a pharmacy record. If the entry is not made by any of the means specified in subdivision (1), (2), (3) or (4) of this

subsection, the pharmacist shall communicate the product dispensed to the prescriber using either facsimile, telephone or electronic transmission, provided such communication shall not be required when a refill prescription is not changed from the product dispensed on the prior filling of the prescription. The provisions of this subsection shall not apply to interchangeable biological products dispensed by a pharmacy operated by a hospital licensed in accordance with the provisions of chapter 368v.

(n) Each prescription for an interchangeable biological product that is delivered to a patient through mail, shipment or parcel delivery service shall contain a written notice to the patient detailing the specific interchangeable biological product being shipped, the name of the pharmacist or pharmacy providing the prescription and contact information, including, but not limited to, a telephone number the patient may call to: (1) Request to be present or have a representative present to sign for delivery of the interchangeable biological product, (2) confirm receipt of the interchangeable biological product, or (3) ask questions regarding the prescription.

[(j)**]** (o) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

Sec. 2. (NEW) (*Effective October 1, 2017*) Prior to prescribing a biological product, as defined in section 20-619 of the general statutes, as amended by this act, a prescribing practitioner shall discuss with the patient or a representative of the patient the treatment methods, alternatives to and risks associated with the use of such biological product. The prescribing practitioner shall document such discussion in the patient's medical record not later than twenty-four hours after such discussion has taken place.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2017*	20-619

Sec. 2	*October 1, 2017*	New section

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

The provisions of the bill are not anticipated to result in a fiscal impact to the state employee or retiree health plan because biological product substitutions are not foreseen given the structure of the pharmacy benefit. Specifically, under the current three-tiered structure (generic, brand, and preferred brand) all biologics are in the preferred brand tier with identical out-of-pocket costs to the consumer. Secondly, the structure of the pharmacy plan does not provide for savings to be passed on to the consumer (e.g. purchaser), which is a condition of substitution in subsection (h) of the bill. The provisions of the bill are not anticipated to result in a fiscal impact to municipal health plans.

There is no cost to the Department of Consumer Protection adopting regulations regarding substituting biological products as the agency has expertise in this area.

House "B "struck the underlying bill and its associated fiscal impact and resulted in the impact described above.

The Out Years

There is no anticipated fiscal impact in the out years assuming no changes to the structure of the pharmacy benefit plan.

OLR Bill Analysis

sHB 7118 (as amended by House "B")*

AN ACT CONCERNING BIOLOGICAL PRODUCTS.

SUMMARY

This bill generally allows pharmacists to substitute a biological product for a prescribed biological product as long as the substitute is an interchangeable biological product and the prescribing practitioner has not prohibited the substitution. It extends to these substitutions many of existing law's provisions on substituting brand name with generic drugs.

The bill also establishes requirements applicable only to biological and interchangeable biological products. Specifically, before prescribing a biological product, a practitioner must discuss with a patient or the patient's representative the treatment methods, alternatives to, and risks associated with using the product. This discussion must then be documented in the patient's medical record within 24 hours. A dispensing pharmacist must inform a patient, or the patient's representative, of a substitution upon dispensing an interchangeable biological product and has 48 hours to also inform the prescriber. The bill requires pharmacists to record certain information about the interchangeable biological products they dispense and make the information accessible to prescribing practitioners. And it sets notice requirements for delivering these products by mail or delivery service.

A "biological product" is generally a virus; therapeutic serum; toxin or antitoxin; vaccine; blood or blood component or derivative; allergenic product; protein, but not a chemically synthesized polypeptide; or arsphenamine or a derivative of it, which is used to

prevent, treat, or cure a human disease or condition.

The bill also makes minor and technical changes, including removing (1) the option for a generic drug prescription label to have the distributor's name instead of the manufacturer's name and (2) an unnecessary definition for "antiepileptic drug."

*House Amendment "B" (1) adds the provisions on mail delivery; (2) shortens the timeframes for notifying patients and prescribing practitioners of substitutions; (3) requires prescribing practitioners and dispensing pharmacists to document certain discussions in patients' health records; and (4) makes other minor and technical changes, including eliminating an unnecessary definition for "antiepileptic drug."

EFFECTIVE DATE: October 1, 2017

BIOLOGICAL PRODUCT SUBSTITUTION

Interchangeability

The bill defines "interchangeable biological product" as a biological product that (1) the federal Food and Drug Administration (FDA) has licensed and determined meets the interchangeability standards under federal law or (2) is therapeutically equivalent to another biological product, as set forth in the latest edition of, or supplement to, its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (see BACKGROUND).

Under federal law, a biological product is considered interchangeable if the FDA finds that it is (1) biosimilar (i.e., highly similar, other than minor differences in inactive components, with no meaningful differences in safety, purity, and potency) to the original licensed product and (2) expected to produce the same clinical result in any given patient. For biological products administered to a patient more than once, there must be no greater risk of switching between the biological product and the original licensed product than if only the original product is used.

Notification

Under the bill, upon dispensing an interchangeable biological product, a pharmacist or his or her authorized agent must inform the patient or the patient's representative of the substitution. The pharmacist must also notify the prescribing practitioner of the substitution, by fax, telephone, or electronic transmission, within 48 hours after dispensing the product. And the pharmacist has 48 hours after dispensing the product to document the substitution by making an entry into an electronic record (see below).

Delivery by Mail

The bill requires that prescriptions for interchangeable biological products delivered to a patient through mail, shipment, or parcel delivery service have a written notice providing the patient with:

1. the specific product being shipped;

2. the name of the pharmacist or pharmacy providing the prescription; and

3. contact information, including a telephone number for the patient to request that someone sign for delivery, confirm receipt of a product, or get information about the prescription.

Before having an interchangeable biological product delivered by these means, the bill requires a pharmacist to contact the patient or his or her representative by telephone to indicate when the product will arrive. The patient or representative may require that they be present to sign for the product's delivery. The pharmacist then has 48 hours to document compliance with these additional notice requirements in the patient's medical or pharmacy record.

Prohibiting Substitutions

Under the bill, practitioners may prohibit substitutions for prescribed biological products in the same way that existing law authorizes them to prohibit substitutions for brand name drugs. Generally, this means that:

1. for written prescriptions, the practitioner must specify on the prescription form "no substitution" or that the prescribed biological product is "brand medically necessary";

2. for telephoned prescriptions, the pharmacist must write "no substitution" or "brand medically necessary" on the prescription or enter it in the electronic prescription record; and

3. for electronic prescriptions, the practitioner must select the "dispense as written" code on the electronic prescription form.

No cost savings. Under the bill, as is the case for drug product substitutions, there must be a cost savings to the purchaser for an interchangeable biological product substitution to occur. If a patient asks, the pharmacist must disclose the savings amount.

Purchaser objection. Like drug product substitutions, the bill also allows purchasers to reject an interchangeable biological product substitution.

Epilepsy or seizure treatment. The bill extends to filling prescriptions for biological products existing law's limitations on filling prescriptions for prescribed drugs to treat epilepsy or prevent seizures. Specifically, it prohibits filling the prescription by using a different manufacturer or distributor unless the pharmacist (1) gives prior notice of the substitution to the patient and the prescribing practitioner and (2) receives written consent from the practitioner.

ELECTRONIC RECORDS

The bill requires pharmacists, or their designees, within 48 hours after dispensing an interchangeable biological product, to record its name and manufacturer in a way that notifies the prescribing practitioner. The information may be made available through:

1. an interoperable electronic medical records system,

2. an electronic prescribing technology,

3. a pharmacy benefit management system, or

4. a pharmacy record.

If an entry is not made by one of the above means, the pharmacist must let the prescriber know about the dispensed product, by fax, telephone, or electronic transmission. However, no such communication is necessary when (1) a refill prescription is the same as the originally dispensed product or (2) the product is dispensed by a hospital pharmacy.

MISCELLANEOUS PROVISIONS

Labels

As under existing law for drug product substitutions, the bill requires pharmacists to label the prescription containers of dispensed interchangeable biological products with the product name. If the product has no "brand name," the label must include the product's nonproprietary name and its manufacturer's name. But prescribing practitioners may instruct pharmacists to withhold the name of the biological product from the prescription label.

Signs

Under existing law, pharmacies must post signs, near counters where prescriptions are dispensed, informing purchasers that they may substitute less expensive and therapeutically equivalent drug products. The bill requires pharmacies to amend their signs to include the same information about interchangeable biological products.

Regulations

The bill requires the consumer protection commissioner, with help from the Commission of Pharmacy, to amend the department's regulations to carry out the bill's provisions.

BACKGROUND

Approved Drug Products with Therapeutic Equivalence Evaluations

The *Approved Drug Products with Therapeutic Equivalence Evaluations* publication identifies drug products approved by the FDA on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 17 Nay 0 (03/07/2017)

Public Health Committee

Joint Favorable
Yea 21 Nay 5 (04/10/2017)